

Application No. 09/424,498
Amendment dated October 6, 2003
Reply to Office Action of April 4, 2003

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-30. (canceled)

31. (currently amended) A pharmaceutical preparation for treating blood coagulation disorders, said preparation comprising a pharmaceutically effective amount of von Willebrand Factor (vWF) propeptide and having been treated for at least one of virus inactivation and virus removal so the preparation is suitable for therapeutic administration.

32. (previously presented) A preparation as set forth in claim 31, said preparation consisting essentially of vWF propeptide.

33-34. (canceled)

35. (previously presented) A preparation as set forth in claim 31, further comprising a hemostasis protein.

36. (previously presented) A preparation as set forth in claim 35, wherein said hemostasis protein is a blood factor.

37. (previously presented) A preparation as set forth in claim 36, wherein said blood factor is selected from the group consisting of mature vWF, factor VIII, activated blood coagulation factors, and blood factors with factor VIII inhibitor bypassing activity.

38. (canceled)

39. (previously presented) A preparation as set forth in claim 31, further comprising a platelet component.

40. (previously presented) A preparation as set forth in claim 39, wherein said platelet component is at least one component selected from the group consisting of collagen, a platelet glycoprotein, a platelet, fibrinogen, fibrin, heparin and a derivative thereof.

41. (previously presented) A preparation as set forth in claim 31, further comprising a phospholipid.

42. (canceled)

43. (previously presented) A preparation as set forth in claim 31, further comprising a pharmaceutically acceptable carrier.

44. (previously presented) A preparation as set forth in claim 31, wherein said vWF propeptide is a recombinant vWF propeptide.

45. (withdrawn) A method for producing a pharmaceutical preparation containing an effective amount of vWF propeptide, said method comprising providing a source material containing said vWF propeptide, separating said vWF propeptide from said source material, and formulating said vWF propeptide to a pharmaceutical preparation.

46. (withdrawn) A method as set forth in claim 45, further comprising subjecting said vWF propeptide to at least one of a virus inactivation and a virus removing treatment.

47. (withdrawn) A method as set forth in claim 45, wherein said source material is selected from the group consisting of plasma and a plasma fraction.

48. (withdrawn) A method as set forth in claim 45, wherein said source material is obtained from a cell culture.

49. (withdrawn) A method as set forth in claim 45, wherein said vWF propeptide is produced by recombinant DNA technology.

50. (withdrawn) A method as set forth in claim 45, wherein said vWF propeptide is contained in a pro-vWF.

51. (withdrawn) A method as set forth in claim 50, wherein said pro-vWF is a mutant pro-vWF with a mutation at the cleavage site of the vWF propeptide.

52. (withdrawn) A method as set forth in claim 50, further comprising providing an inhibitor inhibiting cleavage of said vWF propeptide from said pro-vWF, said pharmaceutical preparation being produced in the presence of said inhibitor.

53. (withdrawn) A method as set forth in claim 45, wherein said vWF propeptide is separated from said source material by chromatography.

54. (withdrawn) A method as set forth in claim 53, wherein said chromatography is an affinity chromatography.

55. (withdrawn) A method as set forth in claim 54, further comprising using carrier materials with ligands specific for said vWF propeptide for said affinity chromatography.

56. (withdrawn) A method for treating a patient running a risk of a blood coagulation disorder comprising administering an effective dose of a pharmaceutical composition comprising at least one of a vWF propeptide and a pro-vWF containing said vWF propeptide to said patient.

57. (withdrawn) A method for treating and preventing blood coagulation disorders in a patient, comprising administering to said patient an effective dose of a pharmaceutical composition comprising at least one of a vWF propeptide and a pro-vWF containing said vWF propeptide.

58. (withdrawn) A method as set forth in claim 57, wherein said patient is a vWD inhibitor patient.

59. (withdrawn) A method of improving the compatibility of pharmaceutical vWF preparations, wherein at least one agent selected from the group consisting of pp-vWF and pro-vWF is administered to a patient when a pharmaceutical vWF preparation is administered to said patient.

60. (withdrawn) A method of treating or preventing adverse effects of endogenous or exogenous vWF, wherein a pharmaceutical composition containing one of pp-vWF and pro-vWF is administered to a patient in an effective dose.

61. (withdrawn) A method as set forth in claim 60, wherein said adverse effects are selected from the group consisting of elevated vWF levels associated with thrombotic thrombocytopenic purpura, Henoch-Schönlein Purpura, preclampsia, neonatal thrombocytopenia, hemolyticuremic syndrome, myocardial infarction and a poor outcome following arterial surgery.

62. (withdrawn) A method as set forth in claim 57, wherein said patient suffers from hemophilia.

63. (withdrawn) A method as set forth in claim 52, wherein said hemophilia is selected from the group consisting of phenotypic hemophilia, hemophilia A and factor VIII inhibitors.

64. (currently amended) ~~A preparation as set forth in claim 31, wherein the vWF propeptide is at least 98% pure.~~ A pharmaceutical preparation for treating blood coagulation disorders, said preparation comprising von Willebrand Factor (vWF) propeptide that is at least 80% pure and has been treated for at least one of virus inactivation and virus removal so the preparation is suitable for therapeutic administration.

65. (currently amended) A preparation as set forth in claim ~~31~~ 64, wherein the vWF propeptide is at least 95% pure.

66. (previously presented) A preparation as set forth in claim 31, further comprising at least two components, wherein the components are selected from the group consisting of a blood factor, a platelet component and a phospholipid.

67. (currently amended) A pharmaceutical preparation for treating blood coagulation disorders, said preparation comprising a pharmaceutically effective amount of pro-von Willebrand Factor (pro-vWF) and having been treated for at least one of virus inactivation and virus removal so the preparation is suitable for therapeutic administration.

68. (previously presented) A preparation as set forth in claim 67, wherein said pro-vWF is a recombinant pro-vWF.

69. (previously presented) A preparation as set forth in claim 67, further comprising factor VIII, said pro-vWF being complexed to said factor VIII.

70. (canceled)

71. (canceled)

72. (previously presented) A pharmaceutical preparation as set forth in claim 31, wherein the preparation is formulated for parenteral administration.

73. (previously presented) A pharmaceutical preparation as set forth in claim 67, wherein the preparation is formulated for parenteral administration.

74. (new) The pharmaceutical preparation as set forth in claim 64, wherein the vWF propeptide is at least 90% pure.

75. (new) A pharmaceutical preparation for treating blood coagulation disorders, the preparation comprising at least 10 nM von Willebrand Factor (vWF) propeptide and having been treated for at least one of virus inactivation and virus removal so the preparation is suitable for therapeutic administration.

76. (new) The pharmaceutical preparation as set forth in claim 75, wherein the preparation comprises at least 50 nM vWF propeptide.

77. (new) A pharmaceutical preparation for treating blood coagulation disorders, the preparation comprising at least 10 nM pro-von Willebrand Factor (pro-vWF) and having been treated for at least one of virus inactivation and virus removal so the preparation is suitable for therapeutic administration.

78. (new) The pharmaceutical preparation as set forth in claim 77, wherein the preparation comprises at least 100 nM pro-vWF.